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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/941,970	08/29/2001	Ashok Rampal	RLL-170US	7742

26815 7590 11/19/2002

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/941,970	RAMPAL ET AL.
	Examiner Micah-Paul Young	Art Unit 1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) This action is **FINAL**.      2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1,2 and 5-12 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1,2-5-12 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____.
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.	6) <input type="checkbox"/> Other: _____

## DETAILED ACTION

### *Papers Received*

Priority Document received 02/26/02, Information Disclosure Statement dated 08/26/02 and Amendment dated 08/26/02.

### *Claim Rejections - 35 USC § 103*

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
3. Claims 1, 2, 5 – 10 and 12 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Balkin (USPN 5,656,284) in view of Urquhart et al (USPN 4,81,232). Balkin teaches an oral controlled release formulation comprising xanthan or locust bean gum (column 4, lines 5-10; claim 17) and erythromycin or clarithromycin (column 7, lines 44-46). Balkin also teaches that the gum/organic polymer equivalent to be present in 1.5% w/w concentration, with the medicament making up 50% of the w/w of the tablet (column 4, lines 20-27; column 8, lines 30-44). Though Balkin does not claim xanthan gum as its organic polymer it is suggested and therefore leaves the claimed invention obvious. Also though applicant has amended the claims to recite a more narrow range, the specification allows for concentration of the active as low as 10% and most preferably 50%. It is the opinion of the examiner that the newly amended ranges of 66% - 90% merely represent the optimum concentrations. It has been held that where the

general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

Urquhart et al teaches a tablet with the suggested embodiment comprising a hydrophilic hydrogel and a drug. The hydrogel is suggested to be sodium alginate (column 5, line 4-7) while the drug is suggested to be erythromycin (column 8, lines 6-14). Though Urquhart is silent to the inclusion of derivatives of erythromycin (clarithromycin) in the suggested embodiment, the reference does teach some of the same rate controlling polymers as Balkin, which has been stated previously to be obvious over the claimed invention. Balkin and Urquhart share teachings of various carbohydrate gums as rate-controlling polymers (column 5, lines 5-10) in conjunction with erythromycin and clarithromycin. Although a cellulose polymer is claimed, these polymeric materials are art accepted as substitutable and it would have been obvious to do so at the time of the invention. One of ordinary skill in the art would have been motivated to combine the suggestions of Urquhart and Balkin because of the expandability and hydrophilicity of sodium alginate.

With regard to the polymers recited by claims 9 and 10, it has been stated above Urquhart teaches a tablet with many possible interchangeable embodiment suggestions. The reference suggest the use of a hydroxypropylcellulose ether or a Carbopol ® (column 5, lines 10-18; column 6, lines 26-28) as a hydrophilic rate-controlling polymer. Urquhart's deficiencies have been previously stated, along with Balkin teachings of obviousness. One of ordinary skill in the art would have been motivated to combine the suggestions of Urquhart and Balkin because of the expandability and hydrophilicity of both hydroxypropylcellulose ether or Carbopol ®.

Claim 12 is drawn to a process for preparing a formulation of erythromycin or a derivative thereof, suitable for a single dosage, comprising a rate controlling polymer and the erythromycin. Balkin teaches, as the preferred embodiment of its tablet, the mixing of the pharmaceutical with the polymer producing a tablet (column 8, lines 48-59). Though this process is not claimed it is suggested by the specification and would have been obvious to one of ordinary skill in the art at the time of the invention. One of ordinary skill in the art would have been motivated to follow Balkin's suggestions of mixing the polymer with erythromycin in order to maximize the interactions between the polymer and active agent.

It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings and suggestions of Balkin with the teachings of Urquhart with the expected result of a pharmaceutical tablet with antibacterial qualities and appropriate carriers for the antibacterial agent.

In view of the art presented the claims remain obviated by the prior art.

Claim 11 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Al Razzak et al (USPN 6,010,718). Al-Razzak teaches controlled release formulation comprising clarithromycin in a single does, once-a-day, at a concentration of 500mg to 1000mg (col. 5, lin. 5 – 7). This however is an optimal concentration similar to that of applicant, and as stated above the determination of optimum ranges, through routine experimentation does not impart patentability. One of ordinary skill in the art would have been motivated to follow the teachings and suggestions of the reference in order to optimize the dosage of the preparation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow

Example 1 with the expected result of a pharmaceutical tablet with antibacterial qualities and appropriate carriers for the antibacterial agent.

In view of the art, the claim remains obviated by the art.

***Response to Arguments***

4. Applicant's arguments filed 08/21/02 have been fully considered but they are not persuasive. Applicant argues that:
  - a. Neither Balkin nor Urquhart provides a suggestion to make a single dosage form of clarithromycin.
  - b. Al-Razzak does not provide motivation for the single administration of the invention.
5. With regard to argument a, Balkin and Urquhart each teach the controlled release of erythromycin and its derivatives in combination with various controlled release polymers. Balkin teaches the polymer concentrations of applicant, though these concentrations do not impart patentability to the claims to which the reference obviates. The references are used to show that controlled formulations for oral use comprising clarithromycin, and various control release polymers (cellulose derivative, gums, and ethers) are well known in the art, and their administration can be determined by skilled artisans through routine experimentation. The mechanism by which the drugs are released is irrelevant with regard to the obviation of the claims, since this element (release mechanics) is not claimed. Applicant only limits invention by stating that the formulation be controlled released. Applicant further points out that Urquhart comprises higher concentrations of the control polymers. Urquhart is only presented to show the

combination of the specific release polymers and a erythromycin derivative. A skilled artisan would be able to construct a dosage form to particular need through routine experimentation.

6. With regard to argument b, Al-Razzak provides sufficient suggestion in that it is within the level of skill in the art to produce various pharmaceutical preparations containing various amounts of an active agent. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971). Al-Razzak suggest a single-dosage administration, a skilled artisan would be able to obtain a single dosage administration following this suggestion through routine experimentation.

*Conclusion*

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 703-308-7005. The examiner can normally be reached on M-F 7:30am-4: 30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-746-7648 for regular communications and 703-746-7648 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Micah-Paul Young  
Examiner  
Art Unit 1615

MPY  
November 17, 2002

THURMAN K. PAGE  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600  
*[Handwritten signature of Thurman K. Page]*